SEP 1 1 2001

DADE BEHRING

Summary of Safety and Effectiveness Information K012233

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's Name Elaine H. Kindell
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Date of Preparation: July 12, 2001

Device Name: Stratus® CS Troponin I Calibrator (cTnI Cal Pak)

FDA Classification Name: Calibrator, secondary

Predicate Device: Stratus® CS TROP CalPak (K983722)

Device Description: The Stratus® CS cTnI CalPak is a plastic cartridge, which contains buffered bovine protein with native human troponin complex in three of the reagent wells. The approximate concentration to troponin complex per well is 40 ng/mL. The CalPak is a single-use product.

Intended Use: The Cardiac Troponin I Calibrator (cTnI CalPak) is intended to be used for calibration of the cardiac troponin I method on the Stratus® CS analyzer.

Comparison to Predicate Device:

Item	Stratus ® CS cTnI Cal Pak (modified)	Stratus ® CS TROP Cal Pak (K983722)
Intended Use	Calibrator	Calibrator
Analyte	Native human troponin complex	Native human troponin complex
Matrix	Normal human serum	Buffered bovine protein
Form	Frozen	Frozen
Target Concentration	40 ng/mL	40 ng/mL
Values	Assigned	Assigned
Packaging Configuration Values	Single use plastic cartridge	Single use plastic cartridge
Levels	One	One

Comments On Substantial Equivalence: The Stratus® CS cTnI CalPak (modified) is equivalent to the Stratus® CS TROP CalPak (K983722) currently marketed. The modified Stratus® CS cTnI CalPak has uses with a normal human serum base versus the buffered bovine protein matrix and associated stabilizers used in the currently marketed product. Both products are intended to be used as calibrators for the Stratus® CS Cardiac Troponin I method.

Conclusion: The modified Stratus® CS cTnI CalPak is substantially equivalent to the Stratus® CS TROP CalPak currently marketed by Dade Behring based on the comparison summarized above.

Elaine H Kindell

Elaine H. Kindell
Quality Assurance and
Compliance Manager
Date: July 12, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Elaine H. Kindell
Quality Assurance and Compliance Manager
Dade Behring Inc.
Glasglow Business Community
P.O. Box 6101, Building 500
Newark, DE 19714

SEP 1 1 2001

Re: k012233
Trade/Device Name: Stratus ® CS Troponin I Calibrator (cTnI CalPak)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: July 12, 2001
Received: July 16, 2001

Dear Ms. Kindell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Stratus® CS Troponin I Calibrator (cTnI CalPak)

Indications for Use: The Cardiac Troponin I Calibrator (cTnI CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the cardiac troponin I method on the Stratus® CS analyzer. This calibrator is a device intended to establish a point of reference that is used in the determination of troponin I values.

Elaine H Kindell
Elaine H. Kindell
Quality Assurance and
Compliance Manager

July 12, 2001
Date

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper
(Division Sign-C
Division of Clin ices
510(k) Number K012233

K012233
510(k) Number

Office of Device Evaluation

Division Sign-Off

Prescription Use ✓ OR Over-the-counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)